

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 68-70, 79-93, 98-100, 104-108, and 110-129 are pending in the application, with claim 68 being the independent claim. Claim 109 has been canceled without prejudice to or disclaimer of the subject matter therein in favor of amended claim 107. Claims 68, 70 and 119 have been amended to emphasize that the claims encompass a method involving recovery of lysed or intact host cells. Claims 104, 105, and 108 have been amended to change their dependency. Claims 121-124 have been amended to clarify that the host cells being recovered as floating cells are those which undergo a lytic event. Claims 125-129 have been added. It is believed these changes introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicant respectfully requests that the Examiner reconsider all outstanding objections and rejections and requests that they be withdrawn.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 104-106 and 108-111 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for depending from a canceled claim. (Paper 42, p. 2). Applicant respectfully traverses.

Claim 104 has been amended to depend from claim 98, claim 105 has been amended to depend from claim 104, and claim 108 has been amended to depend from claim 99. Claim

109 has been canceled. Claims 106 and 110-111 depend from claims 105 and 108, respectively. Accordingly, the objection is moot.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 68-70, 79-93, 98-100, and 104-120 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly being nonenabled. (Paper 42, p.2). The Office Action stated that the recitation of "recovering those host cells which undergo a lytic event," renders the claims non-enabled because they encompass recovering lysed host cells. (*Id.*, p. 3). Applicant respectfully traverses.

To be enabled for their full scope, claims need not include limitations concerning factors that are within the level of ordinary skill in the art. *In re Skrivan*, 427 F.2d 801, 806 (CCPA 1970); MPEP § 2164.08. Further, a specification needs not teach what is well known in the art. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In the present case, the claims are directed to the selection of a nucleic acid that encodes a cytotoxic T cell epitope of interest, as recited in the preamble to claim 68. The specification provides an example in which a monolayer of cells was contacted with CTLs, causing cells that contain the desired recombinant(s) to undergo a lytic event, and to lift off the monolayer. These floating cells were recovered by washing the monolayer and separately

harvesting the floating cells from the adherent cells.¹ The recombinant virus was then extracted from the harvested, floating cells.

As mentioned in the Preliminary Amendment filed March 13, 2003, the vaccinia vectors used in the present invention package in the cell cytoplasm. Therefore, if a sufficient amount of time is allowed to pass before the cells that are undergoing a lytic event are recovered, they would begin to lyse and the recombinant virus would be released. Released virus could be recovered along with the other constituents of the lysed host cells in a manner similar to or the same as that for the floating cells, for example, by simply collecting the tissue culture medium. In other words, whether the recombinant, replication competent virus were contained in host cells -- *or not* -- either way, the virus could be recovered, for example, by collecting the cell culture medium.² Claim 68 and the dependent claims therefore achieve the purpose recited in the claim 68's preamble, i.e., selection of nucleic acids encoding the recited epitope. Accordingly, the claims are fully enabled. Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Other Matters: Continued Prosecution Application

The Office Action appeared to indicate that a request for continued prosecution under 37 C.F.R. § 1.114 was filed on March 13, 2003. (Paper 42, p.2). However, Applicant points

¹ Applicant notes that other methods for recovering cells undergoing a lytic event, such as cell sorting, for example, were known prior to the filing date, and need not have been taught in the specification. "To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for 'preferred' materials . . . would not serve the constitutional purpose of promoting progress in the useful arts." *In re Goffe*, 542 F.2d 564, 567 (CCPA 1976); MPEP § 2164.08.

² In addition, several other methods of recovering lysed cell constituents such as released virus were known when the present application was filed.

out that a Continued Prosecution Application Under 37 C.F.R. § 1.53(d) ("CPA") was filed on that date. Because this application was filed before May 29, 2000, and no CPAs had been filed in this application after May 29, 2000, Applicant believes the CPA filed March 13, 2003 was proper. Additionally, the Corrected Filing Receipt mailed March 31, 2003 indicates that a CPA was filed on March 13, 2003. Applicant respectfully requests acknowledgment that a CPA was filed on March 13, 2003.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding objections and rejections and further requests that they be withdrawn. Applicant believes that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully
requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Helene C. Carlson
Agent for Applicant
Registration No. 47,473

Date: October 2, 2003

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

\\ODMA\MHODMA\SKGF_DC1\146129\2